Message

From: Strauss, Linda [Strauss.Linda@epa.gov]

Sent: 11/8/2018 10:30:33 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]
CC: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: RE: Q's on NAM from Pat Rizzuto

ok

From: Beck, Nancy

Sent: Thursday, November 08, 2018 5:29 PM To: Strauss, Linda <Strauss.Linda@epa.gov> Cc: Baptist, Erik <baptist.erik@epa.gov> Subject: Re: Q's on NAM from Pat Rizzuto

Not perfect but I can live with it.

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator Office of Chemical Safety and Pollution Prevention P: 202-564-1273

beck.nancy@epa.gov

On Nov 8, 2018, at 5:27 PM, Strauss, Linda <Strauss.Linda@epa.gov> wrote:

Made edits in red below

From: Beck, Nancy

Sent: Thursday, November 08, 2018 5:00 PM **To:** Baptist, Erik baptist.erik@epa.gov

Cc: Strauss, Linda <Strauss, Linda@epa.gov>; Bertrand, Charlotte <Bertrand, Charlotte@epa.gov>;

Dunton, Cheryl < Dunton. Cheryl@epa.gov>; Hanley, Mary < Hanley. Mary@epa.gov>

Subject: Re: Q's on NAM from Pat Rizzuto

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Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator Office of Chemical Safety and Pollution Prevention P: 202-564-1273

beck.nancy@epa.gov

On Nov 8, 2018, at 4:46 PM, Baptist, Erik Baptist.Erik@epa.gov> wrote:

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Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Strauss, Linda

Sent: Thursday, November 8, 2018 3:34 PM **To:** Beck, Nancy < <u>Beck, Nancy@epa.gov</u>>

Cc: Baptist, Erik <baptist.erik@epa.gov>; Bertrand, Charlotte

<Bertrand.Charlotte@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Hanley,

Mary < Hanley. Mary @epa.gov>

Subject: RE: Q's on NAM from Pat Rizzuto

Here you go. I edited the OCSPP responses more.

Reporter: Pat Rizzuto

Outlet: Bloomberg Environment (BE)

DDL: (Due to reporter 11/7)

Context: I'm beginning to wrap up a special report about federal agencies, in particular EPA's, use of data from in vitro, in silico, and other new approach methodologies. I'd like updates and/or additional information on the items below. If a conversation is best, I'd welcome that. Here are things I've heard about that EPA was working on:

Deliberative Process / Ex. 5

Questions: Can you provide more information about the goals of these webinars. Have the internal ones begun and how often are they held? What will the stakeholders' webinars be designed to accomplish? Do you have a schedule of those? An idea by when you'll start those (later this year???? Early next year??? Later next year???)

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OCSPP:

TSCA NAM webpage. Background: I've heard OPPT plans to expand its webpage https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce.

In what ways will it be expanding the webpage? What additional information do you plan to post? By when? How do you see the webpage evolving?

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OCSPP:

Any other upcoming efforts you'd like to highlight on EPA's expanding use of NAMs/data from NAMs would be welcome.

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Two new NAM projects include:

- 1. Avian Risk Assessment: Traditionally, we have required both acute oral and sub-acute dietary tests in birds. EPA partnered with People for the Ethical Treatment of Animals (PETA) to conduct a retrospective analysis to see if we can confidently assess acute risks to birds with a reduced suite of effects studies focusing on the single oral dose protocol for birds. The results of the analysis indicate that in most cases, acute avian risk can be assessed without conducting the sub-acute dietary test. We are currently considering these results and developing draft guidance on the data requirements.
- 2. Inhalation Risk Assessment: In December, we will convene a Scientific Advisory Panel that evaluates a proposed NAM for refining inhalation risk assessment (https://www.epa.gov/sap/fifra-scientific-advisory-panel-meetings).

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Questions: Could you elaborate on what "new approach methodology"

information EPA expects to get or, perhaps, already has gotten from NIEHS that is relevant to the decisions the EPA needs to make? In other words, what type of data is NIEHS developing that EPA would like to use and how would it use it?

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aisposition and excretion of PTAS from the body.

From: Beck, Nancy

Sent: Thursday, November 08, 2018 3:13 PM **To:** Strauss, Linda < Strauss. Linda@epa.gov>

Cc: Baptist, Erik baptist.erik@epa.gov; Bertrand, Charlotte

<Bertrand.Charlotte@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Hanley,

Mary < Hanley. Mary@epa.gov>

Subject: Re: Q's on NAM from Pat Rizzuto

Can you re-review all of them and make another cut?

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273

beck.nancy@epa.gov

On Nov 8, 2018, at 3:01 PM, Strauss, Linda <<u>Strauss.Linda@epa.gov</u>> wrote:

From: Baptist, Erik

Sent: Thursday, November 08, 2018 3:01 PM

To: Beck, Nancy < Beck. Nancy@epa.gov >; Strauss, Linda

<Strauss.Linda@epa.gov>; Bertrand, Charlotte<Bertrand.Charlotte@epa.gov>; Dunton, Cheryl

<<u>Dunton.Cheryl@epa.gov></u>; Hanley, Mary <<u>Hanley.Mary@epa.gov></u>

Subject: RE: Q's on NAM from Pat Rizzuto

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The current draft is under management review and is anticipated to be released in a matter of weeks.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Beck, Nancy

Sent: Thursday, November 8, 2018 2:51 PM

To: Strauss, Linda <<u>Strauss, Linda@epa.gov</u>>; Bertrand, Charlotte <<u>Bertrand, Charlotte@epa.gov</u>>; Baptist, Erik <<u>baptist, erik@epa.gov</u>>;

Dunton, Cheryl < Dunton. Cheryl @epa.gov>; Hanley, Mary

<Hanley.Mary@epa.gov>

Subject: RE: Q's on NAM from Pat Rizzuto

Deliberative Process / Ex. 5

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator, OCSPP P: 202-564-1273

beck.nancy@epa.gov

From: Strauss, Linda

Sent: Thursday, November 8, 2018 2:42 PM

To: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte

<Bertrand.Charlotte@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>;

Dunton, Cheryl < Dunton. Cheryl@epa.gov>; Hanley, Mary

<Hanley.Mary@epa.gov>

Subject: RE: Q's on NAM from Pat Rizzuto

Reporter needs by 5 or won't accept.

From: Strauss, Linda

Sent: Wednesday, November 07, 2018 4:06 PM

To: Beck, Nancy < Bertrand, Charlotte

<Bertrand.Charlotte@epa.gov>; Baptist, Erik <baptist.erik@epa.gov>;

Dunton, Cheryl < <u>Dunton.Cheryl@epa.gov</u>>; Hanley, Mary

<Hanley.Mary@epa.gov>

Subject: FW: Q's on NAM from Pat Rizzuto

Any edits to this?

Reporter: Pat Rizzuto

Outlet: Bloomberg Environment (BE)

DDL: (Due to reporter 11/7)

Context: I'm beginning to wrap up a special report about federal agencies, in particular EPA's, use of data from in vitro, in silico, and other new approach methodologies. I'd like updates and/or additional information on the items below. If a conversation is best, I'd welcome that. Here are things I've heard about that EPA was working on:

Deliberative Process / Ex. 5

Questions: Can you provide more information about the goals of these webinars. Have the internal ones begun and how often are they held? What will the stakeholders' webinars be designed to accomplish? Do you have a schedule of those? An idea by when you'll start those (later this year???? Early next year??? Later next year???)

Deliberative Process / Ex. 5

OCSPP:

TSCA NAM webpage. Background: I've heard OPPT plans to expand its webpage https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce.

In what ways will it be expanding the webpage? What additional information do you plan to post? By when?

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How do you see the webpage evolving? **Deliberative Process / Ex. 5** OCSPP: Any other upcoming efforts you'd like to highlight on EPA's expanding use of NAMs/data from NAMs would be welcome. **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5
Questions: Could you elaborate on what "new approach methodology" information EPA expects to get or, perhaps, already has gotten from NIEHS that is relevant to the decisions the EPA needs to make? In other words, what type of data is NIEHS developing that EPA would like to use and how would it use it?

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Reporter: Pat Rizzuto
Outlet: Bloomberg
Environment (BE)
DDL: 4 p.m., 10/24 (She
can be flex if we need
more time.)

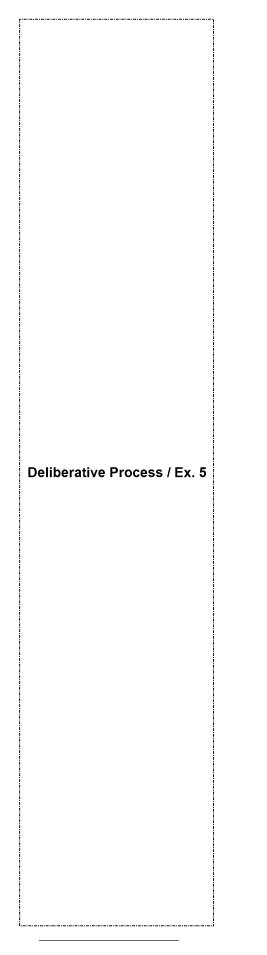
I've broken down what I believe each office is responsible for.

Context:

I'm beginning to wrap up a special report about federal agencies, in particular EPA's, use of data from in vitro, in silico, and other new approach methodologies. I'd like updates and/or additional information on the items below. If a conversation is best, I'd welcome that.

Here are things I've heard about that EPA was working on:

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Susanna W. Blair, PhD
Special Assistant

Prevention and Toxics William Jefferson Clinton Building - East, MC7401M Washington DC 20460 202.564.4371 (office) 202.322.0538 (cell) Blair.susanna@epa

Office of Pollution